REMARKS

Claims 30 and 32-52 are pending.

The descriptive support for inserting "crystalline form" in claims 30, 32, 33, 37-39, 41-44, 48-50 and 52 can be found in the specification at page 7, lines 11-12; page 8, line 17; and page 9, line 20, which disclose that the forms B, A and E of risperidone are crystalline. Applicants submit that there would be no narrowing of the amended claim recitations because one skilled in the art would know that forms B and A are crystalline forms of risperidone.

The descriptive support for inserting "compressed pill" and replacing "table" with "tablet" in claims 35, 40, 46 and 51 can be found in the specification at page 10, lines 6-9. Applicants contend that there would be no narrowing of the amended claim recitations. For instance, the replacement of "table" with "tablet" is done merely to correct a typographical error.

Claim 34 has been amended to remove the dependency on the previously canceled claim 31. The insertion of "in" in claims 34 and 45 is for editorial purposes only.

Claim Rejection -- 35 U.S.C. 112, First Paragraph

Claims 36-38, 41 and 47-49 were rejected because the Office Action takes a position that the use of risperidone in a method of treating psychosis is not described in the specification. Applicants respectfully traverse the written description rejection of claims 36-38, 41 and 47-49. The specification discloses that (a) risperidone is an antipsychotic agent (page 1, line 13), and (b) the risperidone polymorphs of the invention can be administered daily (page 10, lines 5-11). An antipsychotic agent is naturally useful for treating psychosis. In addition, the specification discloses that the risperidone polymorphs of the invention "may be prepared as pharmaceutical compositions that are particularly useful for the management of the manifestations of psychotic disorders" (page 9, the last line to page 10, line 2). Therefore, applicants submit that the inventors were in the possession of the methods of claims 36-38, 41 and 47-49. Withdrawal of the rejection is requested.

Claim Rejection -- 35 U.S.C. 112, Second Paragraph

Claims 34, 35, 40, 41, 46 and 51 were rejected as indefinite.

Claim 34 was rejected because of dependency on the canceled claim 31. The removal of the dependency on claim 31 from claim 34 has rendered the rejection moot.

Claims 35, 40, 46 and 51 were rejected because of the typographical error of "table". Applicants believe that the replacement of the word "table" with "tablet" has rendered the rejection moot because one skilled in the art would readily know the meaning of "sub-lingual tablet."

Claim Objections

Applicants respectfully traverse the objection of claims 32, 33 and 39 as duplicate of claim 30, and the objection of claims 43, 44 and 50 as duplicate of claim 42. Applicants are entitled to claim the invention in a reasonable number of ways. MPEP 706.03(k). A mere difference in scope between claims has been held by courts to be enough to make it proper to claim the invention with more than one claim. *See* MPEP 706.03(k). Applicants respectfully disagree with the Office Action's statement that it is not possible to infringe claim 30 without infringing claim 32, 33 or 39. For a pharmaceutical formulation to literally infringe claim 30, the pharmaceutical formulation must literally meet all the limitations recited in claim 30, i.e., it must comprise a pharmaceutically acceptable carrier and/or a pharmaceutically acceptable excipient and a risperidone crystalline form characterized by the two x-ray powder diffraction (XRPD) peaks recited in claim 30. However, to literally infringe claim 32, a pharmaceutical formulation must comprise a pharmaceutically acceptable carrier and/or a pharmaceutically acceptable excipient and a risperidone crystalline form characterized by the nine XRPD peaks recited in claim 32 in addition to the two XRPD peaks recited in claim 30. A target pharmaceutical formulation that literally infringes claim 30 may not literally infringe claim 32 if the risperidone crystalline form in the target formulation does not have all the XRPD peaks recited in claim 32. Claims 30 and 32 differ in scope. Claims 30 and 39 also differ in scope because the transitional phrase "consists essentially of" in claim 39 would exclude any active ingredient which would materially affect the novel and basic characteristic of the

pharmaceutical dosage form of claim 39, while claim 30 does not have such an exclusion. *See* MPEP 2111.03.

Similar reasoning make it proper for applicants to prosecute claims 43, 44 and 50 in addition to claim 42.

Withdrawal of the claim objections is requested.

Claim Rejections -- 35 U.S.C. 102(b)

Applicants respectfully traverse the anticipatory rejection of claims 30 and 32-52 over Kennis (U.S. Patent No. 4,804,663).

Kennis discloses a genus of compounds of formula I that includes risperidone having antipsychotic properties (column 1, line 24 to column 2, line 8; column 9, lines 19-20; and column 12, lines 21-24). Kennis also discloses an oral solution, capsule, film-coated tablets, injectable solution and suppositories containing any compound of formula I as the active ingredient (Examples 11-15). However, Kennis does not disclose the crystalline forms of risperidone contained in the formulations of claims 30, 32-35, 39, 40, 42-46, 50 and 51, and the crystalline forms of risperidone contained the formulations administered in the methods of claims 36-38, 41, 47-49 and 52.

The Office Action's anticipatory rejection of claims 30 and 32-52 appears to be based on the proposition that any crystalline compound dissolved in a solution is no different from another crystalline form or an amorphous form of the same compound dissolved in a solution because the crystalline forms vanish upon dissolution. Thus, to support the anticipatory rejection of claims 30 and 32-52, the Patent Office seemed to take a position that the formulations of claims 30, 32-35, 39, 40, 42-46, 50 and 51, and the formulations administered in the methods of claims 36-38, 41, 47-49 and 52, are no different from the oral or injectable solutions of the compound of formula I as disclosed by Kennis, if the compound of formula I is risperidone, because the crystalline forms of risperidone recited in claims 30 and 32-52 vanish upon dissolution. However, the Patent Office neglected the fact that, once any of the crystalline forms of risperidone recited in claims 30 and 32-52 completely dissolves in a solution, the resulting solution falls outside of the scope of claims 30, 32-35, 39, 40, 42-46, 50 and 51, and falls outside of the scope of the formulations administered in the methods of

claims 36-38, 41, 47-49 and 52. This is because the risperidone contained in the formulations of claims 30, 32-35, 39, 40, 42-46, 50 and 51, and in the formulations administered in the methods of claims 36-38, 41, 47-49 and 52, must be of the specific crystalline forms recited in the claims. Claims 30 and 32-52 do not recite that the risperidone can be in any physical form. When the specific crystalline forms of risperidone recited in claims 30 and 32-52 completely disappear upon dissolution, the active ingredients of the pharmaceutical formulations are no longer the recited crystalline forms of risperidone. Claims 30, 32-35, 39, 40, 42-46, 50 and 51 do not cover the oral solution or intravenous solution of Kennis, even if the compound of formula I of Kennis is risperidone, because there is no evidence that the oral solution or intravenous solution of Kennis contained any of the specific crystalline forms of risperidone recited in claims 30, 32-35, 39, 40, 42-46, 50 and 51. Claims 30, 32-35, 39, 40, 42-46, 50 and 51 cover pharmaceutical formulations in which at least some of the risperidone molecules exist in any of the crystalline forms recited in the claims. Similarly, the pharmaceutical formulations administered in the methods of claims 36-38, 41, 47-49 and 52 do not include the oral solution or intravenous solution of Kennis. Kennis does not teach the administration of a pharmaceutical formulation, for treating psychosis, containing any of the crystalline forms of risperidone recited in claims 36-38, 41, 47-49 and 52. Withdrawal of the anticipatory rejection of claims 30 and 32-52 is requested.

Conclusion

Allowance of the present claims is respectfully requested. If there are any minor matters that can be resolved with a telephone interview, the Examiner can reach the undersigned at (202) 220-4223 in order to expedite the prosecution.

In the event that the filing of this Response is deemed not timely, applicants petition for an appropriate extension of time. The petition fee and any other fees that may be required in relation to this Response can be charged to Deposit Account No. 11-0600.

Respectfully submitted,
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Date: June 20, 2006

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